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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,062	03/05/2002	Li-Lan H. Chen	366325-524	8011

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EXAMINER
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CHOI, FRANK I

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 07/01/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

10/091,062

Applicant(s)

CHEN ET AL.

Examiner

Frank I Choi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 March 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17, 19-23, 25-48 and 50-53 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

- 6) ☒ Claim(s) 1-17, 19-23, 25-48 and 50-53 is/are rejected.

- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Priority***

Applicant claims priority as a continuation of US Pat. App. 09/619,899. However, the present application while reciting some subject matter similar to the above mentioned application does not appear to be a continuation since the specifications do not appear to recite the same material. For example, US Pat. App. 09/619,899 recites a definition for "solid dispersion" which is not recited in the present application and the number of drawings is different between the two applications. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application.

Applicant does not appear to have addressed the above, as such, Examiner maintains the objection to the claim for priority. Applicant is required to cancel the claim to priority as a continuation of US Pat. App. 09/619,899 or otherwise show that the disclosure does not contain additional material in addition to that of the combined disclosure of US Pat. Apps. 09/619,899, 09/434,878 and 60/116,823, which were incorporated by reference into the present Specification. See MPEP Section 1504.20.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17, 19-23, 25-48, 50-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-17, 20-23, 25-43, 45-48, 50-53 contain the phrase “effective dose of a sexual dysfunction active agent”, however, the Specification (other than sildenafil citrate) does not appear to define what would constitute a sexual dysfunction active agent or effective dose thereof. As such, it does not appear that one of ordinary skill in the art would be reasonable apprised of the scope of the invention.

Examiner has duly considered Applicant’s arguments but deems them unpersuasive.

Applicant asserts that one of ordinary skill in the art would know to look to the Physicians Desk Reference. However, Applicant provides no copy of the relevant pages of the Physicians Desk Reference, which was available at the time the Application was filed, which defines “sexual dysfunction active agent”. Examiner reminds Applicant that the arguments of counsel do not constitute evidence. See *In re Knowlton*, 183 USPQ 33, 37 (CCPA 1974); *In re Wiseman*, 201 USPQ 658 (CCPA 1979).

Claims 7, 33 recite the phrase “a hydration rate in 24 hours of 5-20% at 75% humidity at room temperature” which renders the claim indefinite as it is uncertain what the percent relates to.

Examiner has duly considered Applicant’s arguments but deems them unpersuasive.

As indicated above argument’s of counsel do not constitute evidence. Examiner requests that Applicant provide evidence that one of ordinary skill in the art would recognize that 5-20% refers to increase in mass percent of substance.

Claims 28, 50 recites “an additional active agent” which renders the claims indefinite as it is uncertain whether Applicant means an additional “sexual dysfunction active agent” which may be the same or different from the “sexual dysfunction active agent” or any other active agent. Further, if Applicant intends any other active agent, the claim is ambiguous as it does not

Art Unit: 1616

indicate what the agent is active for. Examiner notes that the Specification recites that active agents include therapeutic agents, nutritional supplements and hygiene aids. Examiner suggests that in this case, Applicant indicate that that active agent is selected from the same.

Examiner notes that the measurement of the properties of the film is based on protocols which are described in the Annual Book of ASTM Standards (1995) and "Dry tack" is measured using Texture analyzers, model TA.XT2i. Examiner is uncertain whether these tests or protocols are recognizable commercial standards or otherwise can be standardized such that one of ordinary skill in the art would be able to determine the scope of the claims herein. As such, Examiner requests copies of the relevant ASTM and relevant manufacturer's specs of the Texture Analyzer, model TA.XT2i, such that they may be readily available should the present Application be issued as a patent.

Examiner has duly considered Applicants arguments but deems them unpersuasive.

Examiner has looked at the web site provided by Applicant, however, this is insufficient as no direction is given as to where the appropriate search terms and/or area in the web site where one would be able to locate the relevant information. Examiner notes that standards are subject to change and the ASTM standard reference in the Specification is from the 1995 publication, so the most recent version of the ASTM is not relevant. A search of texture analyzers and TA.XT2i on the web site did not appear to pull up any relevant information.

#### ***Terminal Disclaimer***

The terminal disclaimer filed on 3/13/2003 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent issued from 09/434,878 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Art Unit: 1616

**Conclusion**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Jose Dees, can be reached on (703) 308-4628. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC

June 28, 2003



JOHN PAK  
PRIMARY EXAMINER  
GROUP 1/60